

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

Plaintiffs,

V.

Case No. 1:14-cv-99-IMK

MYLAN INC. and
MYLAN PHARMACEUTICALS INC.,

Defendants.

**DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICALS INC.'S
RESPONSE TO GILEAD'S MOTION TO DEFER CONSIDERATION
OF MYLAN'S INDEFINITENESS ARGUMENT OR,
ALTERNATIVELY, FOR LEAVE TO FILE A REPLY**

Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, “Mylan”) hereby submit their Response to Plaintiff Gilead Sciences, Inc.’s (“Gilead”) Motion to Defer Consideration of Mylan’s Indefiniteness Argument or, Alternatively, for Leave to File a Reply. Although Mylan does not oppose Gilead’s request for a reply brief, the issue of indefiniteness should be decided during Markman because the claim terms being construed are at the heart of the indefiniteness issue. One has to look no further than the patent and its prosecution history to determine that the claims as a whole, based on the disputed claim terms, are indefinite. No amount of discovery will change the fact that the patent and its prosecution history are silent on the “24-hour” claim terms, and that a person of skill could not determine what was meant by those claims. Moreover, although Gilead was fully aware that Mylan intended to raise indefiniteness during claim construction, even going so far as to reference Mylan’s intent in its own brief, Gilead waited until claim construction briefing was fully completed to even suggest that a ruling on indefiniteness be deferred.

Further, Gilead never argued during the meet-and-confer process that part of the preamble was limiting while the rest was not. Rather, Gilead argued that the entire preamble of the claims directed to a “chemically stable fixed dose combination” was limiting, even offering a construction for *the entire preamble*. Gilead’s approach of including *new* arguments in its opening claim construction brief that are inconsistent with those asserted during the meet-and-confer, namely that the Court should arbitrarily cut the preamble into pieces and construe part of it while ignoring the rest, clearly shows the lengths Gilead will go to in an effort to hide the weakness in its position. The Court should not arbitrarily pick apart the preamble as suggested by Gilead, but rather find the entire preamble as non-limiting.

I. ARGUMENT

A. Plaintiff's Motion to Defer Adjudication of Mylan's Indefiniteness Argument Should be Denied

1. The Court Should Consider Mylan's Indefiniteness Argument During Markman

Gilead's motion to defer is merely an attempt to secure delay despite any showing that factual development could alter the outcome of review of the patents and prosecution history, and despite the views of the Federal Circuit, that indefiniteness is properly part of claim construction. Contrary to Gilead's suggestions, the Federal Circuit has not only recognized that indefiniteness is a part of claim construction, but also approved of indefiniteness determinations at the claim construction stage. *See ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 517 (Fed. Cir. 2012) ("To begin with, indefiniteness is a question of law and in effect part of claim construction."); *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1368, 1374, 1377-78 (Fed. Cir. 2014) (affirming district court's finding of indefiniteness during claim construction); *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1379 (Fed. Cir. 1999) (claim indefiniteness under § 112 ¶ 2 is "inextricably intertwined with claim construction."). The indefiniteness issue regarding the 24-hour claims is ripe for resolution during Markman, because the claim terms at the heart of the argument are being construed. *See Dey, L.P. v. Teva Parenteral Medicines, Inc.*, No. 1:09CV87, 2011 WL 2461888, at *3-4, *6 (N.D. W. Va. Jun. 17, 2011) (Your Honor evaluated Teva's indefiniteness arguments during Markman).

In *Interval*, following a review of the claim language, written description and prosecution history, the district court found certain claims to be indefinite because (1) "the patents fail to provide an objective standard by which to define the scope of [the disputed phrase]"; and (2) "the determination of whether an accused product would meet the claim limitations depends on its usage in changing circumstances." *Interval Licensing, Inc. v. AOL, Inc.*, No. C10-1385MJP,

2013 WL 792791, at *5 (W.D. Wash. Feb. 28, 2013). Like *Interval*, this Court should decide the indefiniteness issue while evaluating the parties' constructions regarding the "24-hour" claim limitations, and find that those claims are indefinite for the reasons stated in Mylan's claim construction brief.

2. Mylan Does Not Oppose Gilead's Request for a Reply Brief Limited to the Issue of Indefiniteness

Gilead's allegation that Mylan's indefiniteness argument was "raised for the first time in Mylan's Answering Claim Construction Brief" is false. Mylan raised its indefiniteness argument during the meet-and-confer process after seeing Gilead's proposed constructions. Adams Decl. ¶ 2. Most telling is the fact that Gilead's opening claim construction brief, which was filed *before* Mylan's answering brief and *specifically references* Mylan's indefiniteness argument. See Dkt. No. 100 at 17, n.7. However, Mylan does not oppose Gilead's request for a reply brief as long as it is limited solely to the issue of indefiniteness. Because it is appropriate to address indefiniteness during claim construction and because Mylan does not oppose Gilead's request for a reply brief, Gilead's motion to defer should be denied.

B. Gilead's Arguments as to Whether Part of the Claim Preamble is Limiting are Unrelated to When the Court Should Resolve Indefiniteness and are Incorrect

In Section C of its motion to defer, Gilead presents an argument that the part of the preamble of the claims directed to a "fixed dose combination" is limiting and that Mylan previously agreed with that point. Gilead's argument is a substantive argument relating to the construction of claim terms. Gilead's preamble argument has nothing to do with the indefiniteness arguments of either party, much less when those should be resolved by the Court. The Court may therefore properly disregard Gilead's unauthorized supplemental brief on

whether the preamble is limiting. However, in the event the Court considers the issue, Mylan will point out below that Gilead is wrong as to whether the preamble is in fact limiting.

The parties' stipulation arose from Gilead's original assertion that the entire preamble was limiting but that only part needed to be construed. The parties' agreed to a construction of "fixed dose combination" at a time when constructions for each of the terms in the preamble were being disputed. The agreement merely resolved a dispute about the construction of a claim term within the preamble, in the event the preamble was limiting. The stipulation did not address whether the preamble, as a whole, was limiting. Mylan did not stipulate to the position now taken by Gilead that part of the preamble is limiting and part is not. Rather, it is Mylan's position that the entire preamble should be non-limiting.

Gilead's January 26, 2015 "List of Claim terms to be Disputed and Proposed Claim Construction of Terms" provided that "chemically stable fixed dose combination" should be construed as "a unit dosage formulation comprising a fixed amount of each active pharmaceutical ingredient in which a first component (such as FTC) of the mixture does not substantially degrade a second component (such as TDF) when the two are physically combined in such a unit dosage formulation." Adams Decl. Ex. 1. Mylan expressed concern that Gilead's proffered construction added an additional limitation to the term, specifically by requiring that a first component does not *substantially* degrade a second component. See Adams Decl. Ex. 2. Gilead's response did not state that it believed that only part of the preamble was non-limiting. See Adams Decl. Ex. 3 ("'**chemically stable fixed dose combination**' – With respect to the 'chemically stable' portion of the claim term, we continue to believe that this phrase does not need construction (or if it does, that Mylan's construction is incorrect)."). In fact, during the meet-and-confer process the parties never discussed whether part of the preamble should be non-

limiting. Adams Decl. ¶ 3. Although the parties agreed during Markman briefing that the “chemically stable” portion of the preamble is non-limiting, that does not change the fact that Gilead failed to indicate during the meet-and-confer process that it intended to treat half of the preamble as limiting and half as non-limiting. Adams Decl. ¶ 4.

As stated in Mylan’s brief, Gilead’s attempt to arbitrarily pick apart the preamble should be rejected. Treating the terms differently is inconsistent with the prosecution history and the claims themselves. *See, e.g.*, Dknt. No. 107 at 6-7; Dkt. No. 107-1, Ex. 5 at 7 (referencing both “chemically stable” and “fixed dose combination”). To be clear, the claim’s full preamble, “chemically stable fixed dose combination,” is non-limiting. *See Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002) (“Generally, the preamble does not limit the claims.”).

II. CONCLUSION

Since Mylan is not opposing Gilead’s request for a reply claim construction brief, Gilead’s Motion to Defer Consideration of Mylan’s Indefiniteness Argument is in part moot. Mylan respectfully requests that the Court deny the remaining portions of Gilead’s motion.

Dated: March 26, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 26, 2015, I filed the foregoing DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICALS INC.'S RESPONSE TO GILEAD'S MOTION TO DEFER CONSIDERATION OF MYLAN'S INDEFINITENESS ARGUMENT OR, ALTERNATIVELY, FOR LEAVE TO FILE A REPLY with the Clerk of the Court using the CM/ECF system, which will send a notice of electronic filing to the attorneys of record for Plaintiffs Gilead Sciences, Inc. and Emory University.

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